

K 970458

MAR - 6 1997

510(k) Summary

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- Introduction** According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.
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- 1. Submitter name, address, contact** Boehringer Mannheim Corporation
2400 Bisso Lane
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(510) 827 - 8215
Fax number: (510) 687-1850
- Contact Person: Patricia M. Klimley
- Date Prepared: January 29, 1997
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- 2. Device Name** Proprietary name: Elecsys® CalCheck™ PSA
Common name: Calibration Verification Material
Classification name: Single (specified) analyte controls (assayed + unassayed)
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- 3. Predicate device** The Elecsys® CalCheck™ PSA is substantially equivalent to currently marketed, Elecsys® CalCheck™ TSH (K963147).
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- 4. Device Description** The Elecsys® CalCheck™ PSA is a three level single analyte set of lyophilized, human based materials. After reconstitution, they are assayed in triplicate and the results compared to the target values.
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510(k) Summary, Continued

**5.
Intended use**

The Boehringer Mannheim Elecsys CalCheck PSA is used to verify the calibration assignment for the Boehringer Mannheim Elecsys PSA assay.

**6.
Comparison
to predicate
device**

The Elecsys® CalCheck™ PSA is substantially equivalent to the currently marketed Elecsys® CalCheck™ TSH (K963147).

The following table compares the Elecsys® CalCheck™ PSA with the predicate device, Elecsys® CalCheck™ TSH. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate devices is provided in attachment 6.

Similarities:

- Configuration: 3 CalCheck levels: low, mid, and high
- Intended use: To verify calibration

Differences:

Feature	CalCheck PSA	CalCheck TSH
Matrix type	Bovine serum albumin	Horse serum
Analyte	PSA	TSH

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**6.
Comparison
to predicate
device, (cont.)**

Performance Characteristics:

- Value assignment and stability
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